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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/757,433	01/15/2004	Horst Ulbricht	02481.1790-01	4111

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EXAMINER
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FUBARA, BLESSING M

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 03/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 10/757,433	Applicant(s) ULBRICHT ET AL.	
	Examiner Blessing M. Fubara	Art Unit 1615	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 10 December 2004.
- 2a) ☐ This action is FINAL.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-6 and 8-44 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6 and 8-44 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

Art Unit: 1615

### **DETAILED ACTION**

Examiner acknowledges receipt of amendment and remarks filed 12/10/04 and applicants' statement of substance of interview (with Examiner on 01/11/05) filed 01/13/05.

Claims 1-6 and 8-44 are pending.

#### Claims copied from published application, US 2003/0012749

Examiner acknowledges applicants' disclosure that claims from US 2003/0012749 were copied into the examined application. Evaluation of interference will be made upon determination of patentable claims.

#### ***Claim Rejections - 35 USC § 102***

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
2. The rejection of claims 1, 2, 4-6, 9-11, 15-18, 20-23, 26-28, 31, 33 and 41-43 under 35 U.S.C. 102(b) as being anticipated by Wohlrab et al. (US 5,346,692) is withdrawn because Wohlrab does not disclose the film forming polymers now recited in the amended claims 1, 17 and 31.
3. Claims 1-6, 9-11, 17-24, 26-29, 31, 35-39, 42 and 43 are rejected under 35 U.S.C. 102(b) as being anticipated by GB 2 202 743.

GB 2 202 743 discloses a varnish formulation that comprises urea, 10% by weight of the total composition and 41% by weight of the non-volatile constituents, EUDRAGIT at 12% by weight of the total composition and 50% by weight of the non-volatile constituents (Example IV). Varnish meets the limitation of a solution or liquid since varnish can be a liquid or solution and the prior art does not define the varnish as other than a liquid or solution. Furthermore, GB

Art Unit: 1615

2 202 743 discloses that the urea is about 1-20% by weight of the total composition, econazole is about 1-2% by weight of the total composition and the resin in the vanish is present at 10-20% by weight of the total composition (last paragraph of page 2, paragraph 1 of page 3, and paragraph 1 of page 5). The amounts above translate to about between 47-83% for the resin and about from 8 to about 64%. Cellulose derivatives (page 3, last paragraph bridging page 4) and polyvinylpyrrolidone/vinyl acetate polymer (last paragraph of page 4) are some of the film forming polymers used in the composition of the GB 2 202 743. GB 2 202 743 meets the limitations of the claims.

4. Claims 1, 8, 15-18, 24, 25, 28-37, 40-44 are rejected under 35 U.S.C. 102(e) as being anticipated by Kraemer et al. (US 2003/0012749, cited by applicants).

Kraemer discloses cosmetic or pharmaceutical composition that comprises urea, film forming hydrophilic polymer and water (abstract, paragraph [0013] and Examples 1-6). The composition may also contain customary cosmetic additives such as plasticizers (paragraph [0019]) and may also contain antimycotic agents (paragraph [0019]). Kraemer discloses that the urea is present in amounts of from 70-90% by weight of the non-volatile constituents and the hydrophilic film former is present in amounts of between 10 and 30% (abstract; paragraph [0015]). A water/alcohol mixture may also be used (paragraph [0022]). Kraemer's lower limit for urea is the upper limit for the instant claim 1. Kraemer meets the limitations of the claims.

#### ***Claim Rejections - 35 USC § 103***

5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Art Unit: 1615

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

7. Claims 2-6, 12-14, 19-23, 26,27, 38, 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kraemer et al. (US 2002/0012749 A1, cited by applicants).

Kraemer discloses cosmetic or pharmaceutical composition that comprises urea, film forming hydrophilic polymer and water (abstract, paragraph [0013] and Examples 1-6).

Kraemer's composition does not contain urea in amounts of less than about 70%. However, generally, differences in amounts of urea will not support the patentability of the subject matter encompassed by the prior art unless there is evidence indicating such amount is critical.

"W[here] the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare the cosmetic composition of Kraemer. One having ordinary skill in the art would have been motivated to prepare the cosmetic formulation of Kraemer and use urea in amounts that would be expected to effectively remove diseased keratin from areas such as toenails and fingernails.

8. Claims 1-6 and 9-43 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Smith (US 5,874,074).

Applicants argue that because Smith's composition/formulation is a lotion, the Smith reference cannot be maintained as art over the instant claims that are directed to solution as the form of the composition. Secondly, applicants argue that Smith is concerned with treating skin diseases and disorders and thus Smith does not disclose treating fingernails and toenails.

Art Unit: 1615

9. Applicants' arguments filed 12/10/04 have been fully considered but they are not persuasive. The method contacts the abnormal keratin with the composition and since the keratinous material is of the skin and Smith applies the composition to the skin, the method of Smith encompasses the instant method and toe and fingers have skin areas. The skin disorders referenced by Smith are psoriasis, eczema, atopic dermatitis, alopecia areata, warts, keratoses (overgrowth of honey tissue) and acne. Regarding lotion vs solution, it is observed that lotion and solution are carriers. Also, in paragraph [008] of page 3 of applicants' disclosure, applicants define a solution as one formed by dissolving urea or optionally suspending the urea in a solvent. Therefore, claiming of a solution does not patentably distinguish over the art-recognized lotion.

#### ***Double Patenting***

10. Claims 17-24 and 26-29 remain provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 17-24 and 26-29 of copending Application No. 10/156,070.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.


Applicants' request that the rejection be withdrawn in the first of the co-pending applications that becomes allowable is noted. However, the examined application has outstanding issues and the claims are not allowable yet. Thus, the rejection is maintained.

Art Unit: 1615

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Blessing Fubara   
Patent Examiner  
Tech. Center 1600